

ClinicalTrials.gov: Record Keeping Tips

Protocol Registration

Verify the study registration

- Before the record is released to ClinicalTrials.gov, or as soon as it is posted on the public site, verify that all of the information in the record is correct
 - Study Type, Study Design and Phase
 - Outcome Measures
 - Study and Primary Completion Dates
 - Arms and Interventions
 - Eligibility
- As the study proceeds, update the information in the record as necessary, particularly when there are Protocol amendments

Submitting Results

Before Entering Results

- Verify that the Protocol information is correct. Update and Release the record before beginning Results if necessary.
- Review some of our help documentation to help you prepare:
 - ClinicalTrials.gov → Submit Studies → How to Submit your Results
 - Results Data Preparation Checklists
 - Simple Results Templates
 - Results Data Element Definitions
 - ClinicalTrials.gov → Submit Studies → Training Materials
 - Example Studies for Results Data Entry
- Do a search on ClinicalTrials.gov for a similar study design

ClinialTrials.gov: Submit Studies

The screenshot shows the ClinicalTrials.gov homepage. The 'Submit Studies' dropdown menu is open, with 'How to Submit Your Results' and 'Training Materials' circled in red. The page includes a search bar, navigation tabs, and various informational sections.

ClinicalTrials.gov
A service of the U.S. National Institutes of Health

ClinicalTrials.gov is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world. [Learn more about clinical studies](#) and [about this site](#), including relevant history, policies, and laws.

Find Studies | **About Clinical Studies** | **Submit Studies** | **Resources** | **About This Site**

ClinicalTrials.gov currently lists **188,076** studies with

Search for Studies
Example: "Heart attack" AND "Los Angeles"

[Advanced Search](#) | [See Studies by Topic](#)
[See Studies on a Map](#)

For Patients & Families

- How to find studies
- See studies by topic
- Learn about clinical studies
- Learn more...

For Researchers

- How to submit
- Download content
- About the results
- Learn more...

Submit Studies

- Why Should I Register and Submit Results?
- FDAAA 801 Requirements
- How to Apply for an Account
- How to Register Your Study
- How to Edit Your Study Record
- **How to Submit Your Results**
- Frequently Asked Questions
- Support Materials
- **Training Materials**
- Learn more...

Locations of Recruiting Studies

Non-U.S. Only (53%)
U.S. Only (42%)
Both U.S. and Non-U.S. (6%)

Total N = 34,953 studies
Data as of April 12, 2015

- [See more trends, charts, and maps](#)

Learn More

- [ClinicalTrials.gov Online Training](#)
- [Glossary of common site terms](#)

[For the Press](#)
 [Using our RSS Feeds](#)

[HOME](#) | [RSS FEEDS](#) | [SITE MAP](#) | [TERMS AND CONDITIONS](#) | [DISCLAIMER](#) | [CONTACT NLM HELP DESK](#)

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U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

<https://clinicaltrials.gov/ct2/manage-recs/how-report>

Results Data Preparation Checklists

ClinicalTrials.gov

A service of the National Institutes of Health

Edited: 19 August 2014

Outcome Measure Data Preparation Checklist

Overview: A tabular summary of outcome measure results by comparison group. You must report tables for each pre-specified primary and secondary outcome and any appropriate statistical analyses. The outcomes that were pre-specified in the Protocol Section of the record will be available to use and edit during results data entry. You may also include other pre-specified and *post hoc* outcomes. Use this checklist with the [Outcome Measure Simple Results Template](#) and [Results Data Element Definitions](#).

	Information to have available for each Outcome Measure	Term
<input type="checkbox"/>	<ul style="list-style-type: none"> Label the measure as Primary, Secondary, Other Pre-specified, or Post hoc. 	* ^Δ Outcome Measure Type
<input type="checkbox"/>	<ul style="list-style-type: none"> Title—Describe specifically what was measured and will be reported as data <ul style="list-style-type: none"> For example, “Change from baseline in systolic blood pressure at 6 months” specifically describes what was measured and how the outcome data will be reported; “Principle Vital Signs” does not. Description—Any elaboration needed to understand the measure and the reported data. Information should be written for a public audience (i.e., not specialists in your field, but general readers of the medical literature). <ul style="list-style-type: none"> For example, a description of how the measure was taken, relevant definitions (e.g., explain “response”), any methods of assessment, and/or calculations that were performed to summarize the data If the measure was based on a scale, explain any numerical categories or provide the range and direction of possible scores (0=no pain; 10=worst possible pain) to allow a reader to properly interpret any reported values. 	* ^Δ Outcome Measure Title ^Δ Outcome Measure Description
<input type="checkbox"/>	<ul style="list-style-type: none"> The time point(s) or duration over which a participant was assessed for the measure, and for which data are being reported <ul style="list-style-type: none"> For a time-to-event measure—A definition of the stopping rule and the longest duration over which a participant was observed (e.g., from randomization until death, up to 3 years) 	* ^Δ Outcome Measure Time Frame
<input type="checkbox"/>	<ul style="list-style-type: none"> The number of separate groups for which summary data will be provided Tip: Generally equal to the number of intervention strategies or groups compared 	Arm/Groups
<input type="checkbox"/>	<ul style="list-style-type: none"> For each group: <ul style="list-style-type: none"> Title—A descriptive label for the group (header for table column). Use informative labels (e.g., “Placebo”), not generic labels (e.g., “Group 1”). Description—A detailed explanation of the participants included in the group and the interventions received. This may include a description of how groups of participants were recombined for analysis purposes. 	* ^Δ Arm/Group Title ^Δ Arm/Group Description
<input type="checkbox"/>	<ul style="list-style-type: none"> Number of participants, in each group, from whom data were collected and summarized. <ul style="list-style-type: none"> If the unit of analysis is not participants, also provide the name of the unit (e.g., eyes, lesions) and the number of units [Type/Number Units Analyzed]. 	* ^Δ Number of Participants Analyzed

Simple Results Templates

* Outcome Measure Type	(Circle One) Primary Secondary Other Pre-specified Post-Hoc	Safety Issue?	(Circle One) Yes No
* Outcome Measure Title			
Outcome Measure Description			
* Outcome Measure Time Frame			

* Arm/Group Title					
Arm/Group Description					
* Number of Participants Analyzed					
Analysis Population Description					
* Measure Type	* Measure of Dispersion/Precision				
(Circle One) Number Mean Median Least Squares Mean Geometric Mean Log Mean	(Circle One) Not Applicable Standard Deviation Inter-Quartile Range Full Range Standard Error 95% Confidence Interval 90% Confidence Interval Geometric Coefficient of Variation				
[*] Category Title					
[*] Category Title					
* Unit of Measure					

Search for a Results Record with a Similar Study Design

The screenshot shows the ClinicalTrials.gov homepage. The browser address bar displays <https://clinicaltrials.gov/ct2/home>. The page header includes the site logo and a description: "ClinicalTrials.gov is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world. Learn more about clinical studies and about this site, including relevant history, policies, and laws." Below the header is a navigation menu with links: Find Studies, About Clinical Studies, Submit Studies, Resources, and About This Site. A status bar indicates that the site currently lists 188,076 studies with locations in all 50 states and in 189 countries. The main content area features a "Search for Studies" section with an example search query "Heart attack" AND "Los Angeles" and a "Search" button. A red circle highlights the "Advanced Search" and "See Studies by Topic" links. To the right of the search section is a "Search Help" section with links: "How to search", "How to find results of studies", and "How to read a study record". Further right is a "Locations of Recruiting Studies" section with a pie chart showing the distribution of study locations: Non-U.S. Only (53%), U.S. Only (42%), and Both U.S. and Non-U.S. (6%). Below the pie chart, it states "Total N = 34,953 studies" and "Data as of April 12, 2015". A link "See more trends, charts, and maps" is provided. The "Learn More" section includes links for "ClinicalTrials.gov Online Training" and "Glossary of common site terms". At the bottom, there are links for "For the Press" and "Using our RSS Feeds". The footer contains a list of links: HOME, RSS FEEDS, SITE MAP, TERMS AND CONDITIONS, DISCLAIMER, and CONTACT NLM HELP DESK. At the very bottom, there is a copyright notice and links to "Privacy", "Accessibility", "Viewers & Players", "Freedom of Information Act", and "USA.gov".

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Find Studies ▾ About Clinical Studies ▾ Submit Studies ▾ Resources ▾ About This Site ▾

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Search for Studies
Example: "Heart attack" AND "Los Angeles"
 Search

Advanced Search | See Studies by Topic
See Studies on a Map

Search Help

- How to search
- How to find results of studies
- How to read a study record

Locations of Recruiting Studies

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U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

During Entering Results

- Use the Help and Definitions links within the PRS

ClinicalTrials.gov PRS
Protocol Registration and Results System

Org: PRS

[Home](#) > [Record Summary](#) > [Results Section](#) > Outcomes

PRSTrainingMaster ID: TTTParallelR Parallel Study Design Example (With Results) [NCT ID not yet assigned]

Outcome Measures Overview

[Results Section](#) [Add Outcome Measure](#) [Reorder Outcome Measures](#) [Help](#) [Definitions](#)

1. Primary Outcome

[Edit](#)

Title:	Change From Baseline in Pain on the 11-point Short Pain Scale (SPS-11) at Week 24
Description:	SPS-11 is a validated, self-reported instrument assessing average pain...
Time Frame:	Baseline and Week 24
Safety Issue?	No

[Delete](#)

[Copy](#)

ClinicalTrials.gov PRS
Protocol Registration and Results System

Org: PRS User:

[Home](#) > [Record Summary](#) > [Results Section](#) > [Outcomes](#) > [Outcome Measure](#) > Edit Data

PRSTrainingMaster ID: TTTParallelR Parallel Study Design Example (With Results) [NCT ID not yet assigned]

Outcome Measure Data

[Help](#) [Definitions](#)

* Outcome Measure Type: Primary

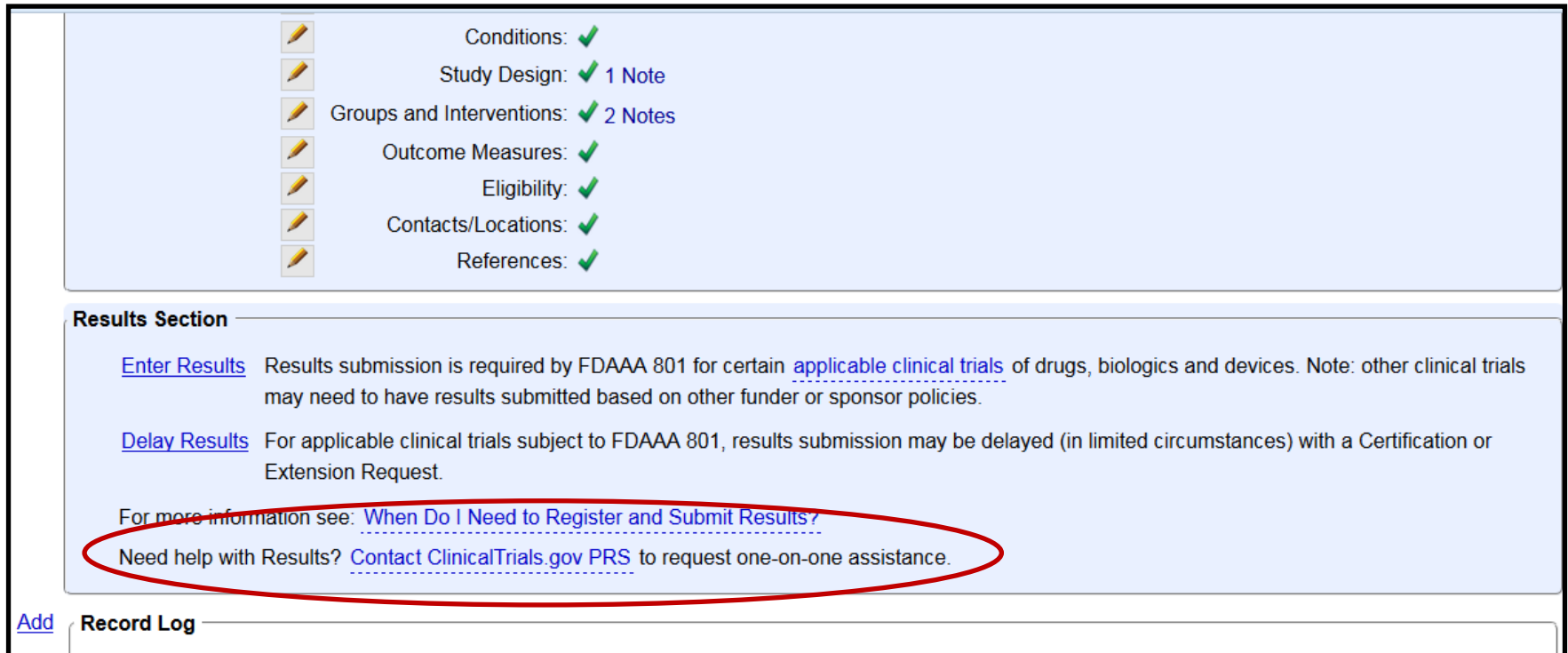
* Outcome Measure Title: Change from Baseline in Pain on the 11-point Short Pain Scale (SPS-11) at Week 24

Outcome Measure Description: SPS-11 is a validated, self-reported instrument assessing average pain intensity over the past

Request 1-on-1 Assistance

ClinicalTrials.gov offers 1-on-1 assistance for investigators throughout the results submission process.

- Contact us using the link at the bottom of the the Record Summary page



The screenshot displays the 'Record Summary' page on ClinicalTrials.gov. At the top, a list of sections with green checkmarks indicates completion: Conditions, Study Design (with 1 Note), Groups and Interventions (with 2 Notes), Outcome Measures, Eligibility, Contacts/Locations, and References. Below this is the 'Results Section'. It contains links for 'Enter Results' and 'Delay Results', each followed by explanatory text. At the bottom of the Results Section, a red circle highlights the text: 'Need help with Results? [Contact ClinicalTrials.gov PRS](#) to request one-on-one assistance.' The 'Add Record Log' button is visible at the bottom left of the page.

Conditions: ✓
Study Design: ✓ 1 Note
Groups and Interventions: ✓ 2 Notes
Outcome Measures: ✓
Eligibility: ✓
Contacts/Locations: ✓
References: ✓

Results Section

[Enter Results](#) Results submission is required by FDAAA 801 for certain [applicable clinical trials](#) of drugs, biologics and devices. Note: other clinical trials may need to have results submitted based on other funder or sponsor policies.

[Delay Results](#) For applicable clinical trials subject to FDAAA 801, results submission may be delayed (in limited circumstances) with a Certification or Extension Request.

For more information see: [When Do I Need to Register and Submit Results?](#)

Need help with Results? [Contact ClinicalTrials.gov PRS](#) to request one-on-one assistance.

[Add](#) Record Log

OR contact us at ANY time via email: register@clinicaltrials.gov